DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

November 17, 1999

Our Reference No.: 98-0207

Loni da Silva
Hoffman-La-Roche, Inc.
340 Kingsland Street
Building 719/4
Nutley, New Jersey 07110-1199

Dear Ms. Da Silva:

Your request to supplement your biologics license application for Interferon alfa-2a to revise the package insert to provide for an induction regimen of 6 MIU three times a week for 12 weeks followed by the standard regimen given for an additional 12 to 36 weeks, has been approved

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We note that you have not fulfilled the requirements of 21 CFR 601.27. We are deferring submission of your pediatric studies until December 2, 2000. However, in the interim, please submit your pediatric drug development plans within 120 days from the date of this letter unless you believe a waiver is appropriate.

Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

This information will be included in your biologic license application file.

Sincerely yours,

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
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Center for Biologics
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